UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

MICHAEL W. HARRIS, et al., Plaintiffs, v. PURDUE PHARMA, L.P., et al., Defendants.	:	NO. 1:01-CV-00428 **ORDER**

This matter is before the Court on Plaintiffs' Motion for National Class Certification (doc. 70), Abbott Defendants' Response in Opposition (doc. 92), Purdue Defendants' Response in Opposition (doc. 93), and Plaintiffs' Reply (doc. 96). The Court held a hearing in this matter on September 18, 2003.

I. Background

This case concerns OxyContin, a federally controlled Schedule II prescription medication, approved by the Food and Drug Administration for the relief of moderate to severe pain. The drug is manufactured by Defendants Purdue Pharma L.P., Purdue Pharma, Inc., the Purdue Frederick Company,(collectively, hereinafter, "Purdue") and co-promoted by Defendants Abbott Laboratories and Abbott Laboratories, Inc. (hereinafter, "Abbott"). Plaintiffs allege that in marketing and promoting OxyContin to physicians, Defendants misrepresented and downplayed risks of addiction (doc. 70). Second, Plaintiffs argue that OxyContin's controlled-release mechanism was defectively designed in that it fails to deliver

consistent and sufficient amounts of oxycodone for the 12-hour dosing period established by Defendants, with resulting fluctuations in oxycodone dispersal exacerbating the risk of addiction (Id.). Third, Plaintiffs argue that Defendants promoted OxyContin by targeting "opioid naive physicians and patients for sales" (Id.).[1] As a part of this negligent or over-promotion argument, Plaintiffs state that Defendants could have designed the drug with a narcotic antagonist that would prevent the crushing of the tablet to bypass the controlled-release mechanism and provide an immediate "high" to abusers. Plaintiffs exclusively seek injunctive relief in the form of a medical and prescription monitoring program for patients prescribed OxyContin, in order to prevent or to mitigate addiction. Plaintiffs presently seek certification of the following class under Fed. R. Civ. P. 23:

> All citizens of the United States who received a prescription for OxyContin and are at risk of addiction as a result, but whom are not presently personal injury claimants or who do not presently have personal injury claims (doc. 77).

II. Class Certification Under Fed. R. Civ. P. 23

The class action serves to conserve the resources of the

[1] The Court understands that the term "opioid naive" refers to a patient that has not yet been prescribed an opioid for the condition causing his pain. Plaintiffs' Motion also refers to "opioid naive" physicians. Plaintiffs argued at the September 18, 2003 hearing that Defendants aggressively marketed the drug to doctors in rural areas. The Court infers from such argument that Plaintiffs' position is that some doctors are "opioid naive" in the sense of failing to understand the potency of the drug they are prescribing.

Court and the parties by permitting an issue that may affect every class member to be litigated in an economical fashion. General Telephone Co. of Southwest v. Falcon, 457 U.S. 147, 155 (1979). The certification of a class action is governed by Federal Rule of Civil Procedure 23, pursuant to which there are four prerequisites:

> One or more members of a class may sue or be sued as representative parties on behalf of all only if : (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.

Although Rule 23(a)(2) refers to common questions of law or fact, in the plural, there need only be one question common to the class–though that question must be a "common issue the resolution of which will advance the litigation." Alkire v. Irving, 330 F.3d 802, 820 (6th Cir. 2003) (citing Sprague v. Gen. Motors Corp., 133 F.3d 388 (6th Cir. 1998)(en banc), and Amchem Prods, Inc. v. Windsor, 521 U.S. 591, 623 (1997). Ultimately, the class may only be certified if, "after rigorous analysis," the district court is satisfied that these prerequisites have been met. Gen. Tel. Co. v. Falcon, 457 U.S. 147, 161 (1982). The burden is on the plaintiff "to establish his right" for class certification. Senter v. General Motors Corp., 532 F.2d 511, 522 (6th Cir. 1976).

If the Plaintiffs can establish the four prerequisites for class certification found in Rule 23(a), numerosity, commonality, typicality, and representativeness, then they must show that, in addition, they satisfy one of the three types of

class actions found in Fed. R. Civ. P. 23(b). A type I class action under 23(b) is appropriate when separate actions would create incompatible standards of conduct for the party opposing the class, or when the interests of members not parties to the litigation would be impeded by individual adjudications. Fed. R. Civ. P. 23(b)(1). A type II class action requires that the plaintiff seek primarily injunctive or declaratory relief. Fed. R. Civ. P. 23(b)(2). A type III class action requires that common questions of law or fact predominate over any issues affecting only individual members and therefore a class action is superior to other available methods for the fair and efficient adjudication of the controversy. Fed. R. Civ. P. 23(b)(3).

Plaintiffs in this case argue that their proposed class meets the four prerequisites of Rule 23(a). They further posit that their class can be certified as type I or II under Rule 23(b)(1)(A) and 23(b)(2), to obtain equitable relief in the form of a national medical and prescription monitoring program.

III. Discussion

A. Plaintiffs' Motion for Class Certification (doc. 70)

Plaintiffs argue that they meet the Rule 23(a) prerequisites as follows:

1) Numerosity. Based on "millions of prescriptions sold" since its introduction in the market, Plaintiffs argue they have established numerosity (doc. 70). Plaintiffs state that 1.8 million people were treated with OxyContin in the year 2000 (Id.).

Plaintiffs state that their expert says that between seven and twenty-eight percent of people prescribed the drug are at risk of addiction (Id.). Plaintiffs argue that it can be inferred that "such a serious epidemic evidences the fact that the number of class members will be in the thousands" (Id.).

2) Commonality. Plaintiffs argue that the class was subject to a common course of conduct by Defendants and proffer three central factual issues and three central legal issues (Id.). Plaintiffs argue that the common factual issues are whether (1) Defendants misrepresented the addiction rate of OxyContin, (2) whether Defendants misrepresented the 12-hour efficacy of the drug, and (3) whether Defendants promoted the drug for inappropriate uses (Id.). As for common legal issues, Plaintiffs posit the following qualify, whether (1) Defendants failed to warn of the true addiction risks associated with OxyContin, (2) whether Defendants' conduct in designing OxyContin contained a defective condition unreasonably dangerous to consumers, and (3) whether Defendants' promotion of OxyContin for allegedly inappropriate uses was negligent (Id.).

3) Typicality. Plaintiffs argue that as their claims arise from the same event or practice or course of conduct of the claims of the class and as the same legal theory applies, they meet the typicality requirement (Id.). Plaintiffs argue that by advancing their interests in seeking a uniform remedy in medical and prescription monitoring, they will advance the interests of the class (Id.).

4) Adequate Representativeness. Plaintiffs argue that as they do not seek individual relief, but rather medical monitoring for all, they meet the adequate representativeness requirement (Id.). As an aside, the Court notes that no one, including the Court, questions the competency or experience of Plaintiffs' counsel to effectively represent the putative class.

Plaintiffs argue next that they meet the requirements of Rule 23(b)(1)(A) because there is a risk of incompatible standards of conduct for Defendants if separate actions were brought (Id.). They argue that because they seek injunctive relief on a class-wide basis, certification under Rule 23(b)(2) is appropriate (Id.). Finally they argue that a medical monitoring program is manageable in three subclasses of strict liability and one subclass of negligence across every state jurisdiction (Id.).

B. Defendants' Memoranda in Opposition (docs. 92 & 93)

Purdue argues that Plaintiffs lack standing because they admit they have no injury, and that any risk of addiction from continued use of the drug cannot, given their knowledge of the reported risk, be caused by Purdue's supposed prior failure to warn (doc. 93). Purdue states that because OxyContin is a Schedule II controlled substance, there are no prescription refills and the patients must regularly see their physicians to get a new prescription (Id.). Further, it is standard medical practice for doctors to monitor their patients for addiction during therapy with opioid drugs (Id.). Consequently, argue Defendants, Plaintiffs are seeking to have Purdue pay for regular doctor visits already

mandated by federal law (Id.).

Purdue insists that it has always warned of the risks associated with OxyContin (Id.). Purdue reproduced on page 6 of its Response the Package Insert Title which states "Warning: May be Habit-Forming" and features the symbol "CII" advising physicians that the drug is a schedule II controlled substance (Id.).

As for Plaintiffs' theory that the time-release mechanism in the drug is defective, Purdue responds that clinical studies contradict Plaintiffs' claims that the drug "stops working" after six to eight hours (Id.). In any case, Defendants argue that two of the proposed Plaintiffs take the drug at twelve hour intervals and neither are addicted, while the two that take the drug at more frequent intervals, did so at the direction of their physicians, a practice for which Purdue cannot be held liable (Id.).

The balance of Purdue's arguments include attacks on the representatives as inadequate, and arguments that a certified national class action would be unmanageable due to differences in the law, and differences in the law specifically as to medical monitoring (Id.). Purdue apparently argues that any misuse of the product, by crushing it, would trigger affirmative defenses including failure to follow directions and contributory negligence. Purdue's attack on Plaintiff's Rule 23 analysis focuses on their position that individual issues predominate over common issues (Id.).

Abbott responded that it did not manufacture, design, label, or sell the drug, and that the lion's share of the exhibits

do not pertain to it (doc. 92). As such, Abbott argues, if there is any claim against it at all, it would only be on a doctor-by-doctor basis, as their interaction in promoting the drug was with doctors (Id.). Additionally, Abbott argues that risk of addiction or fear of future addiction does not constitute an injury-in-fact, and so Plaintiffs lack standing (Id.).

C. Plaintiffs' Reply (doc. 96)

Plaintiffs reiterate that because their claims are for equitable relief only, the case is uniquely suited for class certification (doc. 96). Plaintiffs posit that their claims are based upon common theories for equitable relief applicable to all persons prescribed OxyContin (Id.).

Plaintiffs argue that their experts opine that the risk of addiction for persons prescribed the drug ranges from seven to twenty-eight percent, so that all persons prescribed the drug are exposed to a significant risk of harm through addiction (Id.). Plaintiffs argue that Abbott was a partner in OxyContin's business and thus is jointly and severally liable for everything chargeable to the business (Id.).

Plaintiffs argue that courts frequently approve medical monitoring programs that screen for disease or provide research into public health risks created by defendants' wrongful conduct, citing In re St. Jude Medical, Inc. Silzone Heart Valves Products Liability Litigation, 2003 WL 1589527 (D. Minn. March 27, 2003), In re Diet Drugs Products Liability Litigation , No. 98-20606, 1999 U.S. Dist. LEXIS 13228 (E.D. Pa. Aug. 26, 1999), In re

Telectronics, 172 F.R.D. 271 (S.D. Ohio 1997) (Id.). Plaintiffs argue that such programs are effective, and that Purdue itself has recognized the utility of such a program, having financed a Florida monitoring program for $2 million in exchange for that state's dismissal of a criminal action against it (Id.).

Plaintiffs argue that they have standing because the increased risk of contracting a disease constitutes an "injury in fact" under Friends for All Children v. Lockheed Aircraft Corp., 746 F.2d 816,825 (D.C. App. 1984), and In re Propulsid, 208 F.R.D. 133, 139-140 (E.D. La 2002)("courts have long recognized that an increased risk of harm, which the plaintiff alleges, is an injury-in-fact)(citing Friends for All Children)(Id.).

D. Analysis

For the purposes of this Motion, the Court will presume that Plaintiffs have met the requirement of injury-in-fact and therefore have standing to seek certification of their class. Friends for All Children v. Lockheed Aircraft Corp., 746 F.2d 816,825 (D.C. App. 1984). The Court notes, however, that Plaintiffs' putative class is over-inclusive. As Plaintiffs' expert opines that between seven and twenty-eight percent of those patients taking the drug are at risk of addiction, it logically follows that the inverse is true: between seventy-two and ninety-three percent of those taking the drug are probably not at risk of addiction. As the majority of the people in the proposed class lack an increased risk of harm of addiction, such class members lack a basis for standing. Despite this potential legal infirmity

to Plaintiffs' putative class definition, the practical reality of a medical monitoring program, the remedy sought by the class, is that an entire group of people would need tracking in order to determine the sub-set of those at risk. The Court shall therefore proceed with its class certification analysis.

As an initial matter, the Court notes that many courts presiding over similar products liability cases involving prescription drugs have denied similar requests for class certification. Foister v. Purdue, No. 01-268-DCR, 2002 U.S. Dist. LEXIS 8192 (E.D. Ky., February 26, 2002)(denying certification of an OxyContin class), Gevedon v. Purdue Pharma, 212 F.R.D. 333 (E.D. Ky. 2002)(denying certification of an OxyContin class), In re Paxil Litigation, 212 F.R.D. 539 (C.D. Cal. 2003)(denying motion to certify class of users of a prescription antidepressant and anti-anxiety medication), In re Rezulin Products Liability Litigation, 210 F.R.D. 61 (S.D.N.Y. 2002)(denying motion to certify class of users of a prescription diabetes medication), In re Phenylporpanolamine ("PPA") Products Liability Litigation, 208 F.R.D. 625 (W.D. Wash. 2002), In re Propulsid Products Liability Litigation, 208 F.R.D. 133 (E.D. La. 2002)(denying motion to certify class of users of a prescription heartburn medication), In re Baycol Products Litigation, MDL No. 1431, 2003 U.S. Dist. LEXIS 16341, *17-18 (D. Minn. September 17, 2003)(denying class certification of those who ingested the prescription drug Baycol, noting that the claims involved individual issues such as injury, causation, the Learned Intermediary Doctrine, and comparative

fault), and Valentino v. Carter-Wallace, Inc., 97 F.3d 1227 (9th Cir. 1996). To date, no Court of Appeals decision has approved class certification of an action involving prescription drugs. In re Baycol Products Litigation, 2003 U.S. Dist. LEXIS 16341, *11-12. This Court, as indicated in its concurrently issued order in Wethington v. Purdue, Case No. 1:01-CV-00441, does not find that all pharmaceutical personal-injury products-liability actions are, as an absolute rule, inappropriate for class certification. However, in this case, as in Wethington, the Court finds that the facts militate against class certification.

Fundamentally, the Court finds that Plaintiffs' Motion fails on the Rule 23(a) prerequisite of commonality. In order to satisfy Rule 23(a)(2), there must be "questions of law or fact common to the class." Fed. R. Civ. P. 23(a)(2). The commonality requirement is satisfied "as long as the members of the class have allegedly been affected by a general policy of the defendant and the general policy is the focus of the litigation." Day v. N.L.O., 144 F.R.D. 330,333 (quoting Sweet v. General Tire & Rubber Co., 74 F.R.D. 333, 335 (N.D. Ohio 1976))(emphasis in original). The commonality test is qualitative, not quantitative. 1 Herbert B. Newberg and Alba Conte, Newberg on Class Actions, § 3.10 at 3-50 (3d ed. 1992). There need be only a single question of law or fact common to all members of the class. Id. "[T]he mere fact that questions peculiar to each individual member of the class remain after the common questions of the defendant's liability have been resolved does not dictate the conclusion that a class action is

impermissible." Sterling v. Velsicol Chemical Corp., 855 F.2d 1188, 1197 (6th Cir. 1988). However, the existence of any common question is insufficient because "at a sufficiently abstract level of generalization, almost any set of claims can be said to display commonality." Sprague, 133 F.3d 388, 397 (6th Cir. 1998)(en banc). As noted above, "[w]hat [the court looks] for is a common issue the resolution of which will advance the litigation." Id.

The Court finds that Plaintiffs' three "central factual issues" all relate to whether Defendants misrepresented the efficacy or danger of the drug, or promoted it for inappropriate uses. All such questions pertain to how Defendants marketed the drug. As the Court found in Wethington, Case No. 1:01-CV-00441, it is uncontested that OxyContin is a schedule II opioid drug, and as such, it can only be legally obtained through a doctor's prescription. No one can legally obtain a refill of the drug without seeing a physician. Further, it is standard medical practice for doctors to monitor their patients for addiction during therapy with opioid drugs. Consequently, the Court finds that the existence of individual Learned Intermediaries trumps any common marketing issues. The Plaintiffs would have to prove first that each of their individual physicians was deceived by Defendants' marketing. More precisely, Plaintiff would have to prove whether the individual physician was deceived as to the efficacy, danger, or proper use of the drug, or any combination of those three things. Next, Plaintiff would need to demonstrate whether the physician, as a result of the deception, improperly prescribed the

drug to an individual patient. Finally, the Plaintiff would have to demonstrate that he or she was injured by an increased risk of addiction, having been improperly prescribed or refilled the medication. This entire inquiry is highly individualized. Dhamer v. Bristol-Myers Squibb Co., 183 F.R.D. 520, 529 (N.D. Ill. 1998)(The factual circumstances of addiction are individualized.)

Similarly, the first and third of Plaintiffs' three "central legal issues" turn on failure to warn or negligent promotion, theories that crumble in face of the fact that the drug is clearly labeled "Warning: May be Habit-Forming" and features the symbol "CII" advising physicians that the drug is a schedule II controlled substance. As for Plaintiffs' second legal theory that the time-release mechanism in the drug is defectively designed, the Court finds well-taken Purdue's position that this FDA-approved drug underwent clinical studies showing that the time-release formula worked over a twelve-hour period as designed. Plaintiffs' briefing offers conclusory allegations to the contrary. Plaintiffs proffer neither an expert nor data to show that the time-release mechanism is indeed defective. Moreover, the Court notes that neither of the two proposed class representatives who take the drug at twelve-hour intervals are addicted, while the two that take the drug at more frequent intervals, do so at the direction of their physicians, a practice for which Purdue cannot be held liable. In light of these facts, the Court cannot accept Plaintiffs' second legal theory as a common issue.

The Court further notes that any misuse of the product by

crushing it would trigger further individualized inquiries unique to those class members who abuse the drug. Those class members, too, would be subject to particular affirmative defenses.

The Court does not find well-taken Defendants' arguments that differences in law across state jurisdictional boundaries render such a class action unworkable. The Court is capable of managing such differences. In re Telectronics Pacing Systems, Inc., 172 F.R.D. 271, 287 (S.D. Ohio 1997), mandamus denied, No. 97-3448 (6th Cir. June 11, 1997).

As the Court finds that Plaintiffs' Motion fails on the prerequisite of commonality, the Court need not reach the questions of numerosity, typicality, adequacy of representation, nor conduct a b(2) analysis. However, out of an abundance of caution, the Court shall briefly address the reasons why that even if Plaintiffs could show that the Rule 23(a) prerequisites are met, they have failed to show that the remedy of a medical monitoring program pursuant to Rule 23(b) is appropriate.

Only recently, as signaled by Defendants, the United States District Court for the District of Minnesota rejected the certification of a medical monitoring class for putative class members who had taken the drug Baycol.[2] In re Baycol Products

[2] Use of the drug Baycol allegedly was linked to the development of a number of muscular diseases. In re Baycol Products Litigation, 2003 U.S. Dist. LEXIS 16341, *2-3. In contrast, OxyContin is not alleged to have caused a previously unknown secondary side-effect, but rather to place the patient at risk of addiction, a known risk to the medical community, and a risk clearly labeled on the drug. Moreover, as evidenced by Defendants at the September 18, 2003 hearing, putative class

Litigation, MDL No. 1431, 2003 U.S. Dist. LEXIS 16341, *17-18 (D. Minn. September 17, 2003). The Baycol court found that in evaluating a medical monitoring class, the court must determine whether individual issues exist among the class members that would destroy the cohesive nature of the class claims. Id. citing In re Diet Drugs, 1999 U.S. Dist. LEXIS 13228, at *24 (E.D. Penn. 1999), Thompson v. American Tobacco Company, 189 F.R.D. 544 (D. Minn. 1999), In re Rezulin, 210 F.R.D. at 75. The Baycol court noted that a class will not be cohesive if factual differences amongst the class members "translate into significant legal differences." Id. citing Barnes v. American Tobacco Company, 161 F. 3d 127, 143 (3rd Cir. 1998). Next, the Baycol court noted that though medical monitoring is addressed differently among the states, it appears that whether such a claim is recognized as an independent cause of action, or an element of damages, the state laws generally require a finding that a plaintiff's exposure to a toxic substance was due to a defendant's negligence. Id. citing Redland Soccer Club v. Dept. of the Army, 548 Pa. 178, 696 A.2d 137 (Pa. 1997). The court found that a finding of negligence is inextricably intertwined with individual issues, and therefore that individual issues would undermine the cohesion of the medical monitoring class. Id.

The Court finds the reasoning of the Baycol court

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representative Ronald Fantozi signed a contract with his physician acknowledging the risk of addiction. These facts persuade the Court that there is a stronger case to deny certification of a medical monitoring class in this case than that in the Baycol decision.

instructive in this case. Similarly, this case is riddled with individual issues concerning how the alleged marketing affected the judgment of physicians, how resulting prescriptions affected patients, how some patients allegedly used the drug improperly, and how, at the very least, some eighty-percent of those prescribed the drug have not had nor will have an adverse reaction. As such, the cohesion of the medical monitoring class is in question.

At the September 18, 2003 hearing, the Court queried Plaintiffs as to the utility of setting up an impersonal court-mandated monitoring program as opposed to deferring the judgment of licensed physicians that are already required to monitor their patients. Plaintiffs responded that those addicted to the drug have commonly resorted to the practices of both applying pressure to their doctor to supply more of the drug and/or moving from doctor to doctor in order to obtain another prescription. The Court finds that patients could apply pressure to their physicians to obtain any number of prescription drugs, and that it is ultimately the decision of the physician whether to prescribe or refill the drug. The physician is sophisticated and can ascertain whether pressure from a patient is an indication of addictive behavior, and use his clinical judgment to address the problem. As for the "doctor-hopping" argument, the Court finds that physicians have a duty to examine and question their patients, and are better-placed than any monitoring program to do so. Simply put, as the Court found in Wethington, Case No. 1:01-CV-00441, the Learned Intermediary Doctrine applies squarely to the facts of this

case.[3]

Plaintiffs present well-written arguments concerning the value of prescription drug monitoring databases. The Court does not question the value of such a tool, but is unwilling under the facts of this case to certify a class that could potentially impose the costs of such a program upon the backs of Defendants.

Finally, the Court finds persuasive Defendants' citation to the World Health Organization, for the proposition that drug dependence in patients who take opioids over a long period is rare. Defendants further cite the FDA Anesthetic and Life Support Drugs Advisory Committee, which, on September 9, 2003, stated that "Modified-release, potent opioids, such as Purdue Pharma's OxyContin (oxycodone), should continue to be available to patients with moderate pain."

IV. Conclusion

The Court finds that it is inappropriate to certify

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[3] The Learned Intermediary Doctrine has been adopted by the Ohio Supreme Court and has been applied in product liability actions involving prescription drugs. Seley v. G.D. Serle & Co., 67 Ohio St. 2d 192, 423 N.E. 2d 831 (1981); Tracy v. Merrell Dow Pharmaceuticals, Inc., 58 Ohio St. 3d 147, 569 N.E. 2d 875 (1991). The doctrine operates as an exception to the manufacturer's duty to warn the ultimate consumer and shields manufacturers from liability where the warning to the prescribing physician is adequate. "The rationale behind these holdings is that the physician stands between the manufacturer and the patient as a learned intermediary. The physician has the duty to know the patient's condition as well as the qualities and characteristics of the drugs or products to be prescribed for the patient's use." Tracy, 569 N.E. 2d at 878. In other words the duty to warn is discharged to the physician on the basis of the adequate warnings provided to that physician by the manufacturer.

Plaintiffs' proposed medical monitoring class. Although the Court found that at least a portion of the putative class has standing, having alleged the injury-in-fact of increased risk of addiction, the Court found that the proposed class fails to meet the Fed. R. Civ. P. 23 commonality prerequisite. Moreover, even if the putative class would meet the Rule 23(a) prerequisites, it fails to meet the requirement of Rule 23(b) of cohesiveness. The class is riddled with individual issues, and in particular, fails in the face of the Learned Intermediary Doctrine. The Court does not see how an impersonal court-mandated medical monitoring program is superior to the clinical judgment of individual physicians. Although a prescription database may indeed have great worth, the facts of this case do not support a class certification that could potentially impose liability on Defendants for such a program.

Accordingly, for the reasons herein, the Court DENIES Plaintiffs' Motion for Class Certification (doc. 70).

SO ORDERED.

Dated: September 30, 2003

s/S. Arthur Spiegel
S. Arthur Spiegel
United States Senior District Judge